

## **REMARKS**

Claims 1 to 33 were examined. Claims 1, 2, 27, 28, 30 and 32 have been amended. Claim 34 was added. Claims 1-34 now stand in the application.

Claims 1, 27, 28, 30 and 32 have been amended by replacing the phrase "selected from the group consisting of estradiol, testosterone, and DHEAs" with the phrase "comprises at least four hormones selected from the group consisting of estrogens, testosterone, aldosterone, dehydroepiandrosterone, dehydroepiandrosterone sulphate (DHEAs) and Vitamin D".

Support for the phrase "comprises at least four hormones selected from the group consisting of estrogens, testosterone, aldosterone, dehydroepiandrosterone, dehydroepiandrosterone sulphate (DHEAs) and Vitamin D" is found in the examples which show that 11 steroids were analyzed from different classes of hormones.

Claim 2 was amended to better define the invention by adding a second "wherein" clause.

New claim 34 is directed to the analysis of a multitude of steroid hormones, wherein at least one hormone is an estrogen.

### **Objections based on informalities**

The Examiner objected to claims 1, 27, 28, 30 and 32 recited the acronym "DHEAs". The Examiner states that the claims should be amended to recite "dehydroepiandrosterone sulphates (DHEAs)".

Applicant has amended claims 1, 27, 28, 30 and 32 as requested by the Examiner.

### **Claim rejections 35 USC § 102(b)**

Draisci et al.

The Examiner objected to claims 1-7, 9, 12-16, 18, 21, 25-29 and 32-33 as being anticipated by Draisci et al. The Examiner states that Draisci et al. teaches a method for the quantitation of steroid hormones 17-beta-19-nortestosterone, 17-beta-testosterone and progesterone in a blood serum/plasma or urine sample.

Applicant amended independent claims 1, 27, 28, 30 and 32 by specifying that multitude of steroid hormones comprises at least four hormones selected from the group consisting of estrogens, testosterone, aldosterone, dehydroepicandrosterone, dehydroepiandrosterone sulphate (DHEAs) and Vitamin D.

Applicant has invented a fast and efficient method to analyze a multitude of steroid hormones wherein the steroid hormones are from different classes, for example estrogens, testosterone, DHEAs, etc. The prior art may teach the analysis of a few steroid hormones, but the prior art does not teach the analysis of a wide spectrum of steroid hormones. Applicant has amended the claims to better define the invention and capture the fact that a wide spectrum of hormones can be analyzed by the present invention. Support for the amendment is found in the Examples, in which 9 steroid hormones from different classes of steroid hormones are analyzed. Applicant submits that the objection has been overcome.

Tiller et al.

The Examiner objected to claims 1-5, 9, 12-16, 18, 21, 25-29 and 32-33 stating that Tiller et al. teach a method for the quantitation of testosterone and hydrocortisone using LC-MS.

As stated above, the independent claims have been amended to state that the multitude of steroid hormones comprises at least four hormones selected from the group consisting of estrogens, testosterone, aldosterone, dehydroepicandrosterone, dehydroepiandrosterone sulphate (DHEAs) and Vitamin D. Tiller et al. did not disclose the analysis of four hormones from a wide spectrum of hormones as recited in the amended claims. Applicant submits that the objection has been overcome.

**Claim rejections 35 USC § 103(a)**

Draisci et al., or Tiller et al. in view of Jonsson et al.

The Examiner objected to claims 8 and 10 on the basis of obviousness stating that Jonsson et al. discloses a method and system for the determination of cortisol in saliva and also discloses that a sample can be deproteinated and purified using acetonitrile.

Applicants amended the independent claims by specifying that the multitude of steroid hormones comprises at least four hormones selected from the group consisting of estrogens, testosterone, aldosterone, dehydroepiandrosterone, dehydroepiandrosterone sulphate (DHEAs) and Vitamin D. Jonsson et al. disclosed the analysis of one steroid, cortisol, from saliva. The combination of Draisci et al., Tiller et al and Jonsson et al. would not lead a person of ordinary skill to the claimed invention because neither Draisci et al., Tiller et al. nor Jonsson et al. disclose the analysis of a multitude of steroid hormones from various classes of steroid hormones.

Applicants submit that the rejection has been overcome.

Draisci et al., or Tiller et al. in view of Vogeser et al.

The Examiner objected to claims 11 and 23 on the basis of obviousness stating that Vogeser et al. discloses a method and system for the determination of cortisol in serum by precipitation with methanol and Vogeser et al. also discloses multiple reaction monitoring.

Vogeser et al. disclose the analysis of one steroid (cortisol) in serum samples precipitated with methanol/zinc sulfate in a three step extraction process. Applicants have amended the independent claims by specifying that a multitude of steroid hormones are analyzed from different classes. The combination of Draisci et al., Tiller et al and Vogeser et al. would not lead a person of ordinary skill to the claimed invention because neither Draisci et al., Tiller et al. nor Vogeser et al. disclose the analysis of a multitude of steroid hormones from various classes of steroid hormones.

Draisci et al., or Tiller et al. in view of Alary et al.

The Examiner objected to claims 17 and 19-20 on the basis of obviousness stating that Alary et al. discloses a method of steroid analysis using an atmospheric pressure photoionization source.

Applicants have amended the independent claims by specifying that a multitude of steroid hormones are analyzed from different classes. The combination of Draisci et al., Tiller et al and Alary et al. would not lead a person of ordinary skill to the claimed invention because neither Draisci et al., Tiller et al. nor Alary et al. disclose the analysis of a multitude of steroid hormones from various classes of steroid hormones from a biological sample by the steps recited in the independent claims.

Draisci et al., or Tiller et al. in view of Fredline et al.

The Examiner objected to claims 22 and 24 on the basis of obviousness stating that Fredline et al. discloses a method and system for the determination of aldosterone using a negative ion mode.

Fredline et al. disclose the analysis of one steroid (aldosterone) in plasma or blood samples. Applicants have amended the independent claims by specifying that multitude of steroid hormones are analyzed from different classes. The combination of Draisci et al., Tiller et al and Fredline et al. would not lead a person of ordinary skill to the claimed invention because neither Draisci et al., Tiller et al. nor Fredline et al. disclose the analysis of a multitude of steroid hormones from various classes of steroid hormones.

Draisci et al. and Tiller et al.

The Examiner objected to claims 30 and 31 on the basis of obviousness stating that it would have been obvious for the ordinary skilled worker to incorporate all of the needed/required reagents and instrumentation required for analyzing steroid hormones in accordance with any of the methods taught by the cited art.

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Applicant amended claim 30 by specifying that the kit is for the analysis of a multitude of steroid hormones from different classes. The kit specifies that it comprises four solutions of hormones, selected from the group consisting of estrogens, testosterone, aldosterone, dehydroepiandrosterone, dehydroepiandrosterone sulphate (DHEAs) and vitamin D. Neither Draisci et al. nor Tiller et al. disclose a method for the analysis of steroid hormones from various classes, and therefore neither Draisci et al. nor Tiller et al. would contemplate a kit with these solutions. Accordingly, amended claims 30 and 31 are not obvious over the cited art.


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Applicant believes that all of the issues addressed in the outstanding Action have been addressed in this response, and thus request allowance of the application.

In the event that any issues remain, the Examiner is invited to telephone the undersigned at (416) 865-7367 with any proposal to advance prosecution.

Yours very truly,

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Date



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Attachment: Clean copy of the replacement abstract